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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/18/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/242,215

Applicant(s)

McAnalley et al..

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 17, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6-17, 22, 27-36, and 40-43 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-17, 22, 27-36, and 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 25 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 17, 2002 has been entered.

Acknowledgment is made of Applicant's cancellation of Claims 23-26, 37-39 and 44-47.

Claims 1, 6-17, 22, 27-36, and 40-43 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-17, 22, 27-36 and 40-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide prior support or antecedent basis for the language "wherein said composition is preservative-free and said saccharides are bioavailable as monosaccharides" in claims 1, 22 and 40.

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The claims as set forth in the amendment filed October 17, 2002, now recite a dietary supplement composition comprising nutritionally effective amounts of at least six saccharides, wherein at least one of said saccharides is selected from a first group of saccharides consisting of: galactose, glucose, mannose, xylose and acetylated mannose; and wherein at least one of said saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid and arabinogalactan; and wherein said composition is preservative-free and wherein said saccharides are bioavailable as monosaccharides. However, the specification as originally filed provides only for a dietary supplement composition comprising nutritionally effective amounts of at least six saccharides, wherein at least one of said saccharides is selected from a first group of saccharides consisting of: galactose, glucose, mannose, xylose and acetylated mannose; and wherein at least one of said saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid and arabinogalactan.

Insertion of the above mentioned claim limitations have no support in the as-filed specification. The insertion of the limitations is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of a dietary supplement composition wherein the saccharides are bioavailable as monosaccharides. The Office notes that

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in Paper No. 22 entitled "Amendment After Final; And Response to Office Action Mailed July 24, 2002", Applicant argues under "III. Rejections Under 35 U.S.C. § 102(b)" that the cited prior art as taught by Linscott, Montreuil, Citkowitz, and Ortega fail to anticipate the claimed invention because none of the references disclosed or suggested a dietary supplement composition having the claimed limitation of wherein the saccharides are bioavailable as monosaccharides. Applicant further argues that the referenced dietary supplement could not be the same as the instantly claimed composition because the referenced dietary supplements had not been treated in any manner to make the constituent saccharides of the referenced dietary supplements bioavailable as monosaccharides. However, nowhere in the disclosure of Applicant can be found any teaching or suggestion of a treatment of sources of carbohydrates comprising the claimed saccharides to make the saccharides of the claimed invention bioavailable as monosaccharides. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitations is considered to be the insertion of new matter for the above reasons.

As the above mentioned claim limitations could not be found in the present specification, the recitation of the claim limitations are deemed new matter; and, therefore they must be

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omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 16, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Linscott (A).

Applicant claims a dietary supplement composition comprising nutritionally effective amounts of at least six saccharides, wherein at least one of said saccharides is selected from a first group of saccharides consisting of: galactose, glucose, mannose, xylose and acetylated mannose; and wherein at least one of said saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid and arabinogalactan; and wherein said composition is preservative-free and wherein said saccharides are bioavailable as monosaccharides. Applicant further claims a dietary supplement composition

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according to claim 1, wherein at least one of said saccharides is derived from in oligomeric or polymeric form as found in at least one of the members recited in the Markush group of Claim 6. Applicant further claims a dietary supplement composition according to claim 1, further comprising nutritionally effective amounts of non-toxic vitamins and minerals. Applicant further claims a dietary supplement composition comprising nutritionally effective amounts of at least saccharides, wherein at least one of said saccharides is selected from a first group of saccharides consisting of: galactose, glucose, mannose, xylose; and wherein at least one of said saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, and iduronic acid; and wherein said composition is preservative-free and said saccharides are bioavailable as monosaccharides.

Applicant argues that Linscott fails to anticipate the claimed subject matter because Linscott does not teach that the apple pectin, gum arabic, gum ghatti or guar gum are treated in any manner to make the constituent saccharides of such fibers bioavailable as monosaccharides. However, this is not persuasive because Linscott teaches a granola bar as a dietary supplement fiber, which comprises numerous ingredients including apple pectin (galacturonic acid), gum arabic (arabinose, galactose, and glucuronic acid), gum ghatti (arabinose, galactose, mannose, xylose, and glucuronic acid), and guar gum (mannose and galactose), glucose, rice flour (glucose), and lecithin (see Column 2, lines 12-36 and claims). As the composition taught by

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Linscott comprises rolled oats, crisped rice, chopped almonds, corn bran, etc., non-toxic vitamins and minerals are intrinsically inherent to the composition taught by Linscott.

Applicant points to "Exhibit A" which relates technical information regarding water soluble gums such as gum arabic, gum ghatti and guar gum: "[gums] do not metabolize in the body and thus do not add to caloric count." Thus, Applicant concludes, "[u]nless the fibers disclosed in Linscott '557 are treated in some manner, the constituent saccharides of such fibers are not bioavailable as monosaccharides and certainly have no nutritional effect." However, Applicant's argument is not persuasive because on page 18 in "EXAMPLE 5" and on page 19 in "EXAMPLE 6", Applicant expressly discloses dietary supplement compositions comprising the same constituent ingredients as disclosed by Linscott, e.g., gum ghatti, and gum tragacanth; and, thus the dietary supplement compositions taught by Linscott, which comprise the instantly claimed saccharides inherently must read upon such bioavailable monosaccharides. For example, Applicant discloses a method of making the instantly claimed dietary supplement compositions comprising a mere mixing of the claimed ingredients, which is the same method of making the dietary supplement granola bars taught by Linscott. Moreover, nowhere in the disclosure of Applicant can be found any expressed teaching of treating water soluble gums to make the constituent saccharides of the gums comprising the disclosed compositions bioavailable as monosaccharides.

The reference is deemed to anticipate the claimed subject matter.

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Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Montreuil et al. (B).

Applicant's claimed invention was set forth above.

Applicant argues that Montreuil fails to anticipate the claimed subject matter because Montreuil does not teach or suggest treating the glycoprotein in some manner to make the constituent saccharides bioavailable as monosaccharides. However, this is not persuasive because Montreuil teaches a glycoprotein comprising the monosaccharidic residues: mannose, galactose, fucose, glucose, xylose, N-acetylglucosamine, and N-acetylgalactosamine. Moreover, Applicant's argument is not commensurate in scope to the limitations of the claimed invention. For instance, the instantly claimed invention does not require that a glycoprotein be treated in a manner to make bioavailable the constituent saccharides of the glycoprotein. Moreover, there is no indication that the constituent saccharides of the glycoprotein taught by Montreuil are not bioavailable as monosaccharides. Furthermore, Applicant has not provided a clear and convincing argument that the constituent saccharides of the glycoprotein taught by Montreuil are not bioavailable as monosaccharides.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural

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difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

The reference is deemed to anticipate the claimed subject matter.

Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Citkowitz (U) or Ortega (C).

Applicant claims a dietary supplement composition for providing nutritional product saccharides, which saccharides are essential components of glycoproteins in a mammal, said dietary supplement comprising nutritionally effective amounts of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, and xylose.

Applicant argues that neither Citkowitz nor Ortega teach the instantly claimed dietary composition because the references do not “disclose treating the hyaline layer or the sea urchin eggs to make the saccharides bioavailable as monosaccharides.” However this is not persuasive because Citkowitz teaches that sea urchin embryos comprise the instantly claimed saccharides. See Table 1 on page 496; and, Ortega teaches a dietary supplement comprising sea urchin eggs. The instantly claimed saccharides are intrinsically inherent to the composition taught by Ortega, as evidenced by the teachings of Citkowitz set forth immediately above.

As there is no indication that the constituent saccharides of the referenced compositions taught by Citkowitz and Ortega are not bioavailable as monosaccharides and as Applicant has not

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provided a clear and convincing evidence to suggest otherwise, both of the cited references are deemed to anticipate the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

Michele C. Flood.
MCF

December 16, 2002